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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,706	04/16/2002	Camilo Anthony Leo Selwyn Colaco	8830-23	7593

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EXAMINER	
SHAHNAN SHAH, KHATOL S	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,706	COLACO, CAMILO ANTHONY LEO SELWYN	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 20-22* is/are pending in the application.

4a) Of the above claim(s) *1-13 and 20-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18 and 20-22* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's preliminary amendment received 2/14/2002 is acknowledged. Claims 1-18 and 20-22 have been amended. Claim 19 has been canceled. Abstract of disclosure on a separate page has been submitted.

Election/Restrictions

2. Applicant's election with traverse of April 19, 2004 is acknowledged. Applicant provisionally elected Group II claims 14-18 which are drawn to a vaccine composition.

Applicant explanation that the claims have unity of invention because all claims contain a special technical feature has been noted. The examiner disagrees with the applicant's arguments that the special technical feature of the invention is an immunogenic determinant, which comprises a prokaryotic cell, which has been treated in order to increase the amount of trehalose in the cell. It is the examiner's position as stated in the previous restriction requirement the special feature linking groups I-IV is a method of modifying cells to increase the production of trehalose as recited in the method steps of claims 1-14. The cited prior teach increase in production of trehalose in a cell as the applicants stated in their response (page 3). Therefore, the technical feature linking the inventions of groups I- IV does not constitute a special technical feature as defined by the PCT Rule 13.2, as it does not define a contribution over the prior art.

The requirement is still deemed proper and is therefore made **FINAL.**

3. Currently claims 1-18 and 20-22 are pending.

4. Claims 1-13 and 20-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions.

5. Currently claims 14-18 are under consideration.

Specification

6. The disclosure is objected to because of the following informalities:

7. The words "immunisation" and "immunised" are misspelled in the specification. Immunization is spelled with a "z" not "s". Appropriate corrections are required.

8. The use of the trademarks such as QUIL A and Detox have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Priority

9. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 14-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for induction of trehalose synthesis in some strains (i.e. *E.coli* and

Salmonella typhimurium) of bacteria and production of antibodies in animals against said strains, does not reasonably provide enablement for a vaccine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP) 2164.01(a). Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples (6) the quantity of experimentation, (7) the relative skill of those in the art, and (8) the breadth of the claims.

In the instant case claims 14-18 are drawn to a vaccine. The examples in the specification in pages 12-15 are reciting induction of trehalose production in *E.coli* by osmotic shock (example 1) induction of trehalose production in *Salmonella typhimurium* (example 2) use of the induced cells to immunize mice and rabbits and production of antibodies (examples 3 and 4). The specification does not provide substantive evidence that the claimed vaccines are capable of inducing protective immunity for prevention or treatment of disease. The term "vaccine" encompasses the ability of the specific antigen to induce protective immunity, in the case of the instantly claimed invention, the protection or prevention of infection would be against pathogenic organisms (i.e. bacteria and parasites). When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated base on that limitation. See in re Vaeck, 947 F. 2d 488, 495,20 USPQ 2d 1438, 1444 (Fed Cir, 1991).

Dorland's Medical Dictionary (29th Edition, 2000) defines "vaccine" as "a suspension of attenuated or killed microorganisms (bacteria, viruses, or rickettsiae), or of antigenic proteins derived from them, administered for the prevention, amelioration, or treatment of infectious diseases. In the instant case the applicant's invention is not enabled for the prevention, amelioration, or treatment of all bacterial and parasitic diseases as broadly claimed. The specification page 15 recites growth and induction of *M.bovis*. The specification fails to specify what the vaccine was used for what was the dosage frequency as well as the specific identity of diseases for which the instant invention is applicable (i.e. will be effective for treating or preventing) there has not been provided adequate guidance in the specification for accomplishing and determining such. It is well known in the art that there is currently no vaccine to prevent all bacterial and parasitic infections because of a lack of good animal models for the diseases, a lack of information about the protective antigens, a lack of in vitro correlates to immunity against bacterial and parasitic disease in humans and the pathogenic mechanisms and host immune response to the pathogens has yet to be determined. In the specific disease such as Mycobacterial disease, the history of vaccination in humans against said disease is notorious for a lack of successful protection. In addition, at the time of filing of the instant specification, there remained a lack of correlation of success in animal models with successful vaccination of humans against mycobacterial disease, as evidenced by the review article, "Evaluation of the Protective Potency of New Tuberculosis Vaccines", Review of Infectious Diseases, Vol. 11, Supplement 2, pages S484-S490, March-April 1989.

In summary, it is determined that 1) insufficient direction or guidance is presented in the specification with respect to selecting vaccines having claimed functional feature of capability of generating protective responses, 2) there are no working examples which suggest the desired results of a vaccine against intra-cellular pathogens, 3) the nature of the invention involved the complex and incompletely understood area of protective immune responses against disease, 4) the state of the prior art shows the lack of correlates to immunity with intra-cellular pathogens, 5) the relative skill of those in the art is commonly recognized as quite high (post – doctoral level), and the lack of predictability in the field to which the invention pertains is recognized in the art as evidenced by the cited prior art.

In view of all of the above, in view of the lack of predictability in the art, it is determined that it would require undue experimentation to make and use the invention commensurate in scope with the claims.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

13. Claims 15 and18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is referring to a method of a non-elected claim (i.e. method of claim 1). Claim 15 is indefinite as being dependent from a non-elected claim.

Claim 18 recites the limitation "wherein the induced cells ". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

15. Claims 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Tunnacliff et al. (WO 98/24882).

Claims are drawn to a vaccine composition containing a prokaryotic cell, which contains at least 10mM of trehalose within the cell.

Tunnacliff et al. teach a vaccine composition containing a prokaryotic cell, which contains at least 10mM of trehalose within the cell (see pages 6, 13, 21, and claims specially claims 1, 11 and 21). Tunnacliff et al. teach adjuvants (see page 21), drying in the presence of non-reducing carbohydrates (see claims and page 14). The prior art teaches the claimed composition.

Since the office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed composition and the composition of the prior art (i. e., that the composition of prior art does not possess the same material structure and functional characteristics of the claimed composition). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

16. Claims 14-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Tunnacliff et al. (US 6,468,782).

Claims are drawn to a vaccine composition containing a prokaryotic cell, which contains at least 10mM of trehalose within the cell.

Tunnacliff et al. teach a vaccine composition containing a prokaryotic cell, which contains at least 10mM of trehalose within the cell (see columns 4, 12, 13, 17 and claims specially claims 1, 10, 18-20 and 23). Tunnacliff et al. teach adjuvants (see column 13), drying in the presence of non-reducing carbohydrates (see column 17 and claim10). The prior art teaches the claimed composition.

Since the office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed composition and the composition of the prior art (i. e., that the composition of prior art does not possess the same material structure and functional characteristics of the claimed composition). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645
June 13, 2004

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER